

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK**

**JEANINE A. SORTISIO and STEVEN R.  
SORTISIO,**

**Plaintiffs,**

**v.**

**PETER ACCETTA, M.D., SUSAN M.  
PETERSON, RPA-C, ASTELLAS PHARMA  
US, INC., and NOVARTIS  
PHARMACEUTICALS CORPORATION,**

**Defendants.**

**DEFENDANT  
ASTELLAS PHARMA US, INC.'S  
MEMORANDUM IN  
OPPOSITION TO PLAINTIFFS'  
MOTION TO REMAND**

09-CV-00176-RJA

Hon. Hugh B. Scott

*Document electronically filed.*

Defendant Astellas Pharma US, Inc. ("APUS"), by and through its counsel, submits the following Memorandum in Opposition to Plaintiffs' Motion to Remand:

**I. INTRODUCTION**

Plaintiffs' motion should be denied because APUS properly removed this action on federal-question grounds. Pursuant to 28 U.S.C. § 1331 and *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), this Court has subject-matter jurisdiction over this pharmaceutical product liability action because plaintiffs' allegations that the manufacturing defendants committed fraud on the Food and Drug Administration ("FDA") are substantial issues of federal law.

Plaintiffs allege that defendants APUS and Novartis Pharmaceuticals Corporation ("NPC") (hereinafter "defendants") fraudulently obtained approval from the FDA to release the

prescription medications Protopic<sup>®</sup> and Elidel<sup>®1</sup> into the stream of commerce, and that, as a result, the products injured plaintiff Jeanine Sortisio. *See* Compl. ¶¶ 13-14 (Dkt. #1, Ex. B). Such a claim necessarily alleges that defendants misrepresented or withheld material information under specific provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301, *et seq.*, and its implementing regulations. These allegations, though embedded in a “negligence-styled” cause of action, unmistakably aver a fraud and deceit claim that is independent of any defective product/negligence cause of action and which raises substantial and sharply disputed issues of federal law. Indeed, the United States Supreme Court has held that claims involving fraud on the FDA are “inherently federal in character.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001). Further, finding federal jurisdiction here will not “disturb any congressionally approved balance of federal and state judicial responsibilities[.]” *Grable*, 545 U.S. at 314, because jurisdiction is derived from the specific “fraud-on-the-FDA” allegations in the Complaint. Accordingly, exercising federal jurisdiction in this matter will not sweep garden variety state tort claims into federal court.

APUS’s removal of this action also was procedurally proper. Because no other defendant had been served with a copy of the Summons and Complaint at the time APUS filed its Notice of Removal, pursuant to well-established authority, the other defendants were not required to file written notice of their consent to the removal. Further, plaintiffs have waived any procedural defect by failing to raise it within 30 days of the filing of the notice of removal.

The Complaint necessarily raises substantial and disputed federal issues, justifying removal, and this Court should retain jurisdiction under 28 U.S.C. § 1441(b).

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<sup>1</sup> Protopic<sup>®</sup> and Elidel<sup>®</sup> are FDA-approved prescription medications for the treatment of atopic dermatitis.

## II. BACKGROUND

On February 23, 2009, plaintiffs Jeanine A. Sortisio and Steven R. Sortisio filed a product liability action against APUS, NPC, Peter Accetta, M.D. and Susan M. Peterson, RPA-C, in the State of New York Supreme Court, Erie County alleging, *inter alia*, that Ms. Sortisio suffered personal injuries caused by her use of the FDA-approved pharmaceutical products, Protopic® and Elidel®. *See* Compl. (Dkt. #1, Ex. B). Plaintiffs assert claims based on strict liability, breach of warranty, and negligence. (*Id.* ¶¶ 10-26). Plaintiffs' Complaint includes multiple allegations that implicate federal law and regulations, including allegations that defendants wrongly obtained approval from the FDA to market Protopic® and Elidel®, knowingly engaged in the deceptive design, manufacture, and advertising of the products, and that the FDA-approved labeling was inadequate (*id.* ¶¶ 13-16, 23). On February 27, 2009, prior to service of a copy of the Summons and Complaint on APUS or any other defendant, APUS removed this case to this Court.<sup>2</sup> *See* Not. of Rem. (Dkt. #1).

## III. FEDERAL JURISDICTION EXISTS BECAUSE PLAINTIFFS' CLAIMS NECESSARILY RAISE A SUBSTANTIAL AND DISPUTED FEDERAL QUESTION

### A. State-Law Claims That Raise Significant Federal Issues Are Subject To Federal Jurisdiction

Pursuant to Article III of the Constitution of the United States, the jurisdiction of the federal judiciary extends "to all Cases, in Law and Equity, arising under this Constitution, [and] the Laws of the United States . . . ." U.S. Const. art. III, § 2, cl. 1. In *Cohens v. Virginia*, 19 U.S. (6 Wheat.) 264 (1821), the Supreme Court held that, within the context of Article III, a

<sup>2</sup> For the sake of brevity, APUS addresses solely the threshold substantial federal question presented by plaintiffs' Complaint that defendants fraudulently obtained FDA approval for their products. Because the federal-question ground presented by this claim is sufficient to support removal, APUS does not address here the separate argument presented in the Notice of Removal that plaintiffs' other claims implicate a substantial federal question.

case is “arising under” the Constitution or federal law whenever the “correct decision depends on the construction of either.” *Id.* at 379.<sup>3</sup> Congress first conferred on lower federal courts jurisdiction for cases arising under federal law through the Judiciary Act of 1875. The current version of that law is found at 28 U.S.C. § 1331, which grants district courts “original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. Moreover, a defendant has a right to remove any action of which the district court would have original jurisdiction. *See* 28 U.S.C. § 1441(a).

In *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), the Court held that “arising under” jurisdiction exists over state-law causes of action where “the right to relief depends upon the construction or application of the Constitution or the laws of the United States.” *Id.* at 199. Although some intervening decisions, including *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986), appeared to undermine *Smith*, in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), the Court reaffirmed that “federal question jurisdiction will lie over state-law claims that implicate significant federal issues.” *Id.* at 312. The Court reasoned that this doctrine embraces “the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues . . . .” *Id.* In *Grable*, an essential element of the plaintiff’s state-law quiet title claim was whether the plaintiff had received adequate notice pursuant to federal law that its property had been seized by the IRS to satisfy a federal tax delinquency. The Court held that “the meaning of

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<sup>3</sup> *See also Osborn v. Bank of the United States*, 22 U.S. (9 Wheat.) 738, 823 (1824) (holding that Article III “arising under” jurisdiction extends to all cases necessitating a construction of federal law).

the federal tax provision is an important issue of federal law that sensibly belongs in federal court.” *Id.* at 315.

Since *Grable*, several Courts of Appeals, including the Second Circuit, have held that federal-question jurisdiction exists over state-law claims that, as here, turn on disputed issues arising under federal statutes or complex federal regulatory schemes. *See, e.g., Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194-96 (2d Cir. 2005) (federal-question jurisdiction existed under *Grable* where state-law claims involved “aspects of the complex federal regulatory scheme applicable to cable television rates, as to which there is ‘a serious federal interest in claiming the advantages thought to be inherent in a federal forum’”) (quoting *Grable*); *Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1234-37 (10th Cir. 2006) (finding jurisdiction under *Grable* where state-law trespass and unjust enrichment claims required plaintiff to show that the railroad’s installation of fiber-optic cable along its right-of-way was a misuse of the federally granted right-of-way pursuant to the National Trails System Act); *Pet Quarters, Inc. v. Depository Trust and Clearing Corp.*, 559 F.3d 772, 779 (8th Cir. 2009) (finding jurisdiction over state-law claim that “directly implicate[d] actions taken by the [Securities and Exchange Commission] in approving the creation of [a] Stock Borrow Program and the rules governing it”); *Municipality of San Juan v. Corporacion Para El Fomento Económico De La Ciudad Capital*, 415 F.3d 145, 148 n.6 (1st Cir. 2005) (finding jurisdiction under *Grable* where propriety of defendant’s conduct under state law “turn[ed] entirely on its adherence to the intricate and detailed set of federal regulatory requirements, and the funds at issue [were] federal grant monies”); *PNC Bank, N.A. v. PPL Elec. Utils. Corp.*, 189 F. Appx. 101, 104 n.3 (3d Cir. 2006) (unpublished opinion) (finding federal-question jurisdiction where plaintiff’s “right to relief depend[ed] upon the construction or application of [a section of the Internal Revenue Code]”).

*Grable* explains that there is no “‘single, precise, all-embracing’ test for jurisdiction over federal issues embedded in state-law claims . . . .” *Id.* at 314. Rather, courts should analyze a case based on the following jurisdictional question:

“[D]oes a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities[?]”

*Id.* In accordance with *Grable*, “arising under” removal jurisdiction exists so long as there is a substantial federal issue that is actually disputed and necessary to the resolution of the plaintiff’s claims, and appropriately decided by a federal court. *Id.* As set forth below, because plaintiffs’ state-law claims depend upon the substantial and disputed federal issue of whether defendants committed fraud on the FDA in contravention of their obligations under the FDCA and FDA regulations, federal jurisdiction exists.

**B. Plaintiffs’ Claims Necessarily Raise A Disputed And Substantial Issue Creating Federal Jurisdiction**

A claim that a pharmaceutical manufacturer has knowingly misrepresented information regarding the safety of a prescription drug that may have impacted FDA’s decision to approve the drug for use in the United States is “an important issue of federal law that sensibly belongs in a federal court.” *Grable*, 545 U.S. at 315. Federal-question jurisdiction exists here because plaintiffs’ claims will require them to establish that defendants committed fraud on the FDA, a claim that the United States Supreme Court has explained “exist[s] solely by virtue of the FDCA disclosure requirements” and is “inherently federal and character.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347, 353 (2001).<sup>4</sup>

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<sup>4</sup> FDA is the federal agency charged by Congress in the FDCA with the authority and responsibility to regulate every aspect of the safety, effectiveness, labeling, marketing, and promotion of prescription drugs. *See* 21 U.S.C. § 301, et seq.

Plaintiffs allege that defendants “improperly obtained approval for the drugs known as Elidel<sup>®</sup> and Protopic<sup>®</sup> from the Food and Drug Administration” and “knowingly . . . engaged in the deceptive design, manufacture, production, advertising, promotion, and sale of [these drugs].” Compl. ¶¶ 13-14 (Dkt. #1, Ex. B). The gist of plaintiffs’ allegations is that had FDA known that defendants misrepresented or withheld information from FDA the agency would not have approved the drugs and Jeanine Sortisio would not have used them and been injured. Plaintiffs thus allege a breach of duty owed not only to Jeanne Sortisio, as the consumer, but to a federal agency. This language in the Complaint constitutes a fraud and deceit claim that is an independent and divisible wrong from a defective product/negligence cause of action, and which it will not be possible to adjudicate without determining whether defendants violated numerous FDA regulations. Indeed, nowhere in the Complaint do plaintiffs disclaim their intent to rely on violations of federal law to establish liability in this matter.<sup>5</sup>

Plaintiffs’ allegations that defendants fraudulently obtained FDA approval to market Protopic<sup>®</sup> and Elidel<sup>®</sup> would require the Court to judge defendants’ conduct against “the complex federal regulatory scheme applicable to [prescription drugs], as to which there is a ‘serious federal interest in claiming the advantages thought to be inherent in a federal forum . . . .’” These federal issues are not clearly insubstantial, and [plaintiffs do] not now contend that their merits would be easily resolved in [their] favor.” *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 195 (2d Cir. 2005) (finding federal-question jurisdiction under analogous circumstances). In particular, plaintiffs’ claim would require the Court to examine whether defendants were in compliance with numerous federal disclosure requirements, including, *inter*

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<sup>5</sup> Even if plaintiffs were to disclaim any intent to prove fraud on the FDA, their allegations of improper conduct before FDA and “deceptive” design, manufacture, and sale of these products invoke the same concerns at issue in *Buckman* and thus justify a federal forum.

*alia*: (1) 21 U.S.C. § 355, which sets forth detailed statutory requirements of the information and materials that drug companies must submit to FDA in seeking approval for a new drug; (2) 21 C.F.R. § 314.80, which governs a drug company's disclosure requirements relating to submissions of adverse drug experience reports; and (3) 21 C.F.R. § 314.81, which governs a drug company's disclosure requirements relating to submissions of new studies and various other information relevant to the continued approval of the drug.

As such, plaintiffs' "right to relief" on their fraud/improper approval claim "depends on the construction or application of [the FDCA and its implementing regulations]," the implications of such claims are national in scope, and "the national interest in providing a federal forum . . . is sufficiently substantial to support the exercise of federal-question jurisdiction over the disputed issue on removal." *Grable*, 545 U.S. at 310, 313 (citations omitted). See *West Virginia ex rel. McGraw v. Eli Lilly & Co.*, 476 F. Supp. 2d 230, 233-34 (E.D.N.Y. 2007) (finding jurisdiction under *Grable* in case alleging state-law claims against pharmaceutical company to recover expenditures for drug under Medicaid program); *In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170, 171-73 (E.D.N.Y. 2005) (finding jurisdiction under *Grable* where state-law claims alleged pharmaceutical company improperly promoted drugs for off-label use in violation of the FDCA and its implementing regulations).<sup>6</sup>

The Supreme Court's ruling in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001), moreover, demonstrates the substantial nature of the federal question at issue. In *Buckman*, the Court held that a claim that a defendant knowingly misrepresented information to the FDA was "inherently federal in character because the relationship [between the FDA and

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<sup>6</sup> The character of plaintiffs' fraud/improper approval claim, which involves the alleged misconduct of defendants before a federal agency and has national implications, distinguishes this case from, for example, the contract-based reimbursement claim at issue in *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677 (2006).

manufacturer] originates from, is governed by, and terminates according to federal law.” 531 U.S. at 347. The Court rejected plaintiffs’ argument that their claims sounded solely in state tort law: “[W]ere plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a *critical element* in their case.” *Id.* at 353 (emphasis added).

As the Court explained, a manufacturer’s “dealings with the FDA [a]re prompted by the [FDCA], and the very subject matter of [the manufacturer’s] statements [a]re dictated by that statute’s provisions.” *Id.* at 347-48. The Court reviewed the numerous provisions in the FDCA by which the federal government polices fraud against the FDA, *id.* at 349, and held that there is “clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government.” *Id.* at 352. Indeed, the Court found that “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied . . . .’” *Id.* at 347 (citation omitted).

While *Buckman* addressed federal preemption, and not “arising under” jurisdiction, it nevertheless establishes that claims, such as those here, that involve proof of non-disclosure of material information to the FDA implicate a significant federal interest justifying resort to a federal forum.<sup>7</sup> Further, because FDA has approved Elidel® and Protopic® as safe and

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<sup>7</sup> To be clear, APUS is not asserting that federal-question jurisdiction exists here on the basis of a federal preemption defense. Here, the “federal issue . . . arises in [p]laintiffs’ case-in-chief, not by way of defense.” *Nicodemus*, 440 F.3d at 1235. *See also Grable* (quiet title action required plaintiff to prove that he was not given proper notice of seizure under federal statute). Whether federal jurisdiction exists must be determined by the allegations of the well-pleaded complaint, *U.S. Express Lines, Ltd. v. Higgins*, 281 F.3d 383, 389 (3d Cir. 2002), not by a potential *defense*. Just as a federal defense does not ordinarily give rise to federal-question jurisdiction, a defense should not divest jurisdiction where, as here, the complaint raises significant federal issues.

effective for their indicated uses, as in *Grable*, “[t]he Government thus has a direct interest in the availability of the federal forum to vindicate its own administrative action.” *Id.*<sup>8</sup>

Following *Buckman*, other federal courts addressing state-law tort claims for damages involving allegations of fraud on the FDA have concluded that such claims present inherently federal issues. Recently, in *Grange v. Mylan Laboratories, Inc.*, No. 1:07-CV-107 TC, 2008 WL 4813311 (D. Utah Oct. 31, 2008), the United States District Court for the District of Utah held that “the chief problems that *Buckman* sought to counteract are present whenever a plaintiff, as a prerequisite to collecting damages, is required to put on evidence that there was what amounts to fraud on the FDA.” *Id.* at \*7. Further, “[w]hen such evidence is considered, state courts are essentially second-guessing the FDA and drug companies, nervous about state litigation, will have an incentive to flood the FDA with information.” *Id.* Importantly for our purposes here, the court recognized that in addressing plaintiff’s fraud-on-the-FDA claims “**a state court will have to interpret what information is required under FDA regulations. Such a review will implicate . . . the *Buckman* concerns.**” *Id.* at n.4 (emphasis added). See also *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1172-73 (D. Ariz. 2005) (fraud-on-the-FDA type claims “place state courts, as the finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA’s complicated approval process”).<sup>9</sup>

<sup>8</sup> Were FDA to bring its own action for fraud on the FDA, it would, of course, be litigated in a federal forum. See 21 U.S.C. §§ 331-334, 337. Defendants should not be denied a similar forum simply because plaintiffs raised the issue in the context of a state-law tort claim.

<sup>9</sup> See also *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-66 (6th Cir. 2004) (any difference between a specific cause of action for fraud on the FDA or the need to prove fraud on the FDA as a prerequisite to finding the manufacturer liable on a state-law products liability claim is “immaterial”; state-court proceedings investigating whether a drug manufacturer complied with federal disclosure requirements “would raise the same inter-branch-meddling concerns that animated *Buckman*”); *Henderson v. Merck & Co.*,

Although these courts were not faced with the issue of federal-question jurisdiction, each of them found that claims under state law necessarily implicated substantial federal interests as evidenced by the fact that the courts found such claims preempted in most circumstances. The fact that plaintiffs' fraud-on-the-FDA claim is embedded among claims brought under state law in no way lessens the significance of the federal issues at stake. To prevail on their pleaded claim that defendants "improperly obtained approval for the drugs from the [FDA]" – by fraud, deceit, misrepresentation or otherwise – plaintiffs will have to establish that defendants violated regulations enacted by a federal agency pursuant to authority vested by Congress. Such claims are more appropriately addressed in a federal forum.

The federal interests at stake in *Grable* are analogous. The plaintiff premised its state-law quiet-title action on whether it received adequate notice from the IRS before the seizure of its property; the notice issue was a question of federal tax law; there was a strong federal interest in a federal forum for the vindication of the Government's administrative actions; and the parties to the suit might "find it valuable to come before judges used to federal tax matters," *Grable*, 545 U.S. at 315. Similarly, the Sortisios allege that defendants improperly and deceitfully obtained FDA approval for their products; the Government has a strong federal interest in a federal forum to vindicate FDA's drug approval decisions and in policing disclosures before the FDA; and the parties may find it helpful to have the complex federal regulatory scheme for prescription drugs interpreted by a federal judge familiar with the

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No. 04-CV-05987-LDD, 2005 WL 2600220 (E.D. Pa. Oct. 11, 2005) (following *Buckman* and *Garcia*). But see *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd sub nom*, *Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 1168 (2008) (taking a different view of the Michigan law at issue in *Garcia* and *Henderson*). (The affirmance of *Desiano* was by an equally divided vote and thus is not entitled to any precedential weight.)

application of federal law and regulations. Under *Grable*, plaintiffs' Complaint raises significant federal issues.<sup>10</sup>

**C. Exercising Federal Jurisdiction Over This Matter Does Not Upset The Balance Of Federal And State Judicial Responsibilities**

The last part of *Grable*'s test also is satisfied. The exercise of federal jurisdiction in these narrow circumstances where pharmaceutical manufacturers are alleged to have committed fraud on the FDA and such a claim forms an integral part of the plaintiffs' cause of action, will not "disturb[] any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314.

First, as the Supreme Court has recognized, "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied . . . .'" *Buckman*, 531 U.S. at 347. Issues of fraud on the FDA involve "a somewhat delicate balance of statutory objectives" and the "balance sought by [FDA] can be skewed by allowing fraud-on-the-FDA claims under state-tort law." *Id.* at 348. As such, unusual cases like this one "justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues . . . ." *Grable*, 545 U.S. at 312.

Second, permitting removal based on a claim that FDA approval of prescription medications was fraudulently obtained will not result in a flood of state claims being heard in federal court. Rather, it would only implicate those exceptional cases in which plaintiffs choose to bring claims that require them to prove a violation of FDA disclosure requirements. Under the well-pleaded complaint rule, plaintiffs are "the master of their complaint" and thus are "free to

<sup>10</sup> Because at least one claim in plaintiffs' Complaint supports federal-question jurisdiction, this Court may assert jurisdiction over all the claims since "they form part of the same case or controversy . . . ." 28 U.S.C. § 1367. *See also Broder*, 418 F.3d at 194 ("A single claim over which federal-question jurisdiction exists is sufficient to allow removal.") (citing *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546 (2005)).

avoid federal jurisdiction by pleading only state claims . . . .” *Marcus v. AT&T Corp.*, 138 F.3d 46, 52 (2d Cir. 1998); *Ching v. Mitre Corp.*, 921 F.2d 11, 13-14 (1st Cir. 1990) (“The [well-pleaded complaint] rule makes the plaintiff the master of the claim; he or she may avoid federal jurisdiction by exclusive reliance on state law.”). Though they could have rested their claims on other grounds, the Sortisios took the unusual step of premising their lawsuit on the allegation that defendants defrauded a federal agency to obtain approval to manufacture and market their products.<sup>11</sup> The substantial federal issues involved with plaintiffs’ fraud-on-the-FDA allegations distinguish this case from “garden variety” state-law tort claims and exercising jurisdiction under the particular circumstances here would not “materially affect, or threaten to affect, the normal currents of litigation.” *Grable*, 545 U.S. at 319.

For this reason, plaintiffs’ reliance on *Merrell Dow* is similarly misplaced. *Merrell Dow* specifically retained the “contextual enquiry” of *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), that requires a court to weigh the extent of the federal interest in determining federal-question jurisdiction. *Grable*, 545 U.S. at 317-18 (*Merrell Dow* requires “careful judgments” about the “nature of the federal interests at stake”). Indeed, *Merrell Dow* “disclaimed the adoption of any bright-line rule,” reaffirming that “in exploring the outer reaches of § 1331, determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system.” *Id.* at 317 (quoting *Merrell Dow*).

Further, though a number of federal courts have misinterpreted the case as such, *Merrell Dow* does not stand for the proposition that “arising under” removal jurisdiction requires the existence of an express or implied private, federal right of action. Dismissing this argument, *Grable* emphasized that “*Merrell Dow* cannot be read whole as overturning decades of precedent

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<sup>11</sup> Thus, it should come as no surprise to plaintiffs that APUS believes such a claim, by its very nature and significance, should be heard by a federal judge.

. . . and converting a federal cause of action from a sufficient condition for federal-question jurisdiction into a necessary one.” 545 U.S. at 317 (emphasis in original). Thus, *Grable* reaffirms the historical breadth of “arising under” jurisdiction articulated as far back as *Smith*. See section III(A), *supra*.

Courts have specifically cautioned against using *Merrell Dow* as plaintiffs wish to—as a broad brush with which to paint all pharmaceutical cases. As Judge Weinstein recognized in upholding removal under *Grable* in *In re Zyprexa Products Liability Litigation*, “[t]he specific allegations and subtle distinctions in pleadings among pharmaceutical cases may require exercise of jurisdiction in cases which appear close to, but jurisdictionally different from, *Merrell Dow*.” 375 F. Supp. 2d at 172. This is one such case. Because recognizing federal jurisdiction here is dependent upon the unusual fraud-on-the-FDA allegations in plaintiffs’ Complaint, this case presents significantly less concern than *Merrell Dow*.<sup>12</sup> Simply put, jurisdiction here does not lay a “welcome mat” that would attract “a horde of original filings and removal cases raising other state claims with embedded federal issues.” *Grable*, 545 U.S. at 318. Accordingly, the Court has subject matter jurisdiction under 28 U.S.C. § 1331.

#### IV. THE REMOVAL WAS PROCEDURALLY PROPER

Plaintiffs’ argument that the removal was defective because defendants Peter Accetta, M.D. and Susan M. Peterson, RPA-C did not consent to the removal within 30 days of service is wholly without merit. Plaintiffs do not dispute that at the time APUS filed its Notice

<sup>12</sup> *Caggiano v. Pfizer Inc.*, 384 F. Supp. 2d 689 (S.D.N.Y. 2005), on which plaintiffs rely, also is distinguishable. Unlike in *Merrell Dow* and *Caggiano*, plaintiffs here have alleged that plaintiff’s alleged injury resulted from defendants fraudulently obtaining FDA approval to market their products – a claim that involves alleged violations of duties owed not only to the plaintiff, but to the governing federal agency, and thus which is “inherently federal in character.” *Buckman*, 531 U.S. at 347. As such, this claim falls under the “special circumstances” the *Caggiano* court acknowledged would justify federal-question jurisdiction. *Caggiano*, 384 F. Supp. 2d at 691.

of Removal on February 27, 2009, no other defendants had been served.<sup>13</sup> It is axiomatic that the propriety of removal is determined at the time of removal. See *Tarr v. Town of Rockport*, 405 F. Supp. 2d 75, 77 (D. Mass. 2005) (citing cases). Thus, while the general rule is that all defendants must join in the removal, a well-established exception is that defendants who have not been served at the time of removal need not join. See *Lewis v. Rego Co.*, 757 F.2d 66, 68 (3d Cir. 1985); *Borden v. Blue Cross and Blue Shield of Western New York*, 418 F. Supp. 2d 266, 270 (W.D.N.Y. 2006) (“The rule of unanimity is excused where . . . the non-joining defendants have not been served with service of process at the time the removal petition is filed . . .”). In *Lewis*, the Third Circuit held:

[T]he removal statute contemplates that once a case has been properly removed the subsequent service of additional defendants who do not specifically consent to removal does not require or permit remand on a plaintiff’s motion. The statute itself contemplates that after removal process or service may be completed on defendants who had not been served in the state proceeding. The right which the statute gives to such a defendant to move to remand the case confers no rights upon a plaintiff. 28 U.S.C. § 1448.

*Id.* at 69. See also *Miranti v. Lee*, 3 F.3d 925, 929 (5th Cir. 1993) (defendants who have not been served at the time the notice of removal is filed need not join in the removal); *P.P. Farmers’ Elevator Co. v. Farmers Elevator Mut. Ins. Co.*, 395 F.2d 546, 547-48 (7th Cir. 1968) (same); *Varela v. Flintlock Constr., Inc.*, 148 F. Supp. 2d 297, 300 (S.D.N.Y. 2001) (same); 14A Wright, Miller & Cooper, Fed. Prac. & Proc. § 3731, at 509-10 (1985). Further, the authority cited by plaintiffs regarding the rule of unanimity clearly acknowledges the unserved-defendant exception. See *Owczarek v. The Austin Company, OBH, Inc.*, No. 03-CV-0750E(F), 2004 WL

<sup>13</sup> Defendants Accetta and Peterson were served with a copy of the Summons and Complaint on March 4, 2009. NPC was served with a copy of the Summons and Complaint on March 6, 2009. See Pls.’ Not. of Mot., Affidavit of Theresa M. Walsh, Exs. C-E.

625273, at \*1 n.6 (W.D.N.Y. Feb. 11, 2004). Because no other defendant had been served at the time APUS filed its Notice of Removal, the consent of the other defendants was not necessary. Accordingly, the removal is proper.

Plaintiffs' assertion of a procedural defect in the removal, moreover, is untimely and thus has been waived. Pursuant to 28 U.S.C. § 1447(c), "[a] motion to remand the case on the basis of any defect other than lack of subject matter jurisdiction must be made within 30 days after the filing of the notice of removal under section 1446(a)." APUS filed its Notice of Removal on February 27, 2009; plaintiffs did not file their motion to remand until April 15, 2009, more than 30 days after removal. Accordingly, any assertion of a procedural defect regarding a lack of unanimous consent to removal has been waived. *See Flagler v. Budget Rent A Car Sys., Inc.*, 538 F. Supp. 2d 557, 558 n.1 (E.D.N.Y. 2008) ("[f]ailure to comply with the rule of unanimity in a notice of removal, is, unlike lack of subject matter jurisdiction, a procedural defect that is waived thirty days after the notice of removal is filed.") (citations omitted); *Novick v. Bankers Life Ins. Co. of New York*, 450 F. Supp. 2d 196 (E.D.N.Y. 2006) (plaintiffs waived procedural defect of lack of consent by failing to raise it within 30 days after notice of removal was filed).

## V. CONCLUSION

For all these reasons, the Court should deny plaintiffs' motion and exercise jurisdiction over this case.

DATED: May 8, 2009  
Rochester, NY

Respectfully submitted,

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Sharon M. Porcellio

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